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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/652,493	08/31/2000	Mina J. Bissell	IB-1398	3653

7590

04/23/2002

Patent Counsel  
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EXAMINER

DAVIS, NATALIE A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/652,493

Applicant(s)

BISSELL ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Applicant's amendment filed 3 January 2002 (Paper No: 6) is acknowledged. Accordingly, claims 9-21 and 25-28 are cancelled, and claims 1-8 and 22-24 are pending and under examination.

#### *Response to Arguments*

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Claim Rejections - 35 USC § 112 1<sup>st</sup> Withdrawn*

1. Rejection of claims 1-8 under 35 U.S.C. 112, first paragraph is withdrawn in view of arguments.

#### *Claim Rejections - 35 USC § 103 Maintained*

2. Rejection of claims 22-24 over Matsumura, et al, (1993) under 35 U.S.C. 103<sup>(a)</sup> is maintained for reasons set forth in the previous office action. The traversal is on the grounds that Applicant's arguments have been considered but are not persuasive because Matsumura teach "*laminin-binding 156DAG and 43DAG are encoded by a single gene and are now called  $\alpha$  and  $\beta$ -dystroglycan, respectively*" (abstract) and teach  $\alpha$ -dystroglycan from the brain with a molecular weight of 120kDa (p. 283, col. 2). The reference also discloses antibodies against distinct domains of dystrophin including 156 DAG and 43 DAG (dystroglycan). Since Matsumura teach  $\alpha$ -dystroglycan and antibodies directed to it, such as monoclonal antibody IIH6, it would be reasonable to conclude that the antibodies may be used to detect fragments (120 kDa and/or 60 kDa) of  $\alpha$ -dystroglycan in blood serum.

NAD  
4-22-04

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#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsumura, et al., (1997).

Matsumura, et al., (1997) teach  $\alpha$ -dystroglycan, monoclonal antibodies, such as I1H6 and VIA41, that specifically bind to it and antibodies directed against laminin-1 (p. 13905, col. 2). Matsumura, et al., (1997) further teach the presence of  $\alpha$ -dystroglycan and not  $\beta$ -dystroglycan in the culture medium of rat schwannoma cell line RT4, indicating that a fraction of RT4 cell surface  $\alpha$ -dystroglycan is dissociated and released into culture medium, the detection of  $\alpha$ -dystroglycan using immunocytochemical analysis and SDS PAGE, and the role of  $\alpha$ -dystroglycan in RT4 cell adhesion to laminin-1, wherein RT4 cells cultured on laminin-1 become spindle shaped and adhere to the bottom surface, whereas cells inhibited from binding laminin-1 remain rounded (p. 139807-8). It is inherent that tumorigenecity potential may be measured by detecting the presence of  $\alpha$ -dystroglycan in medium since  $\alpha$ -dystroglycan is shed in a tumorigenic cell line (RT4). It is inherent that  $\alpha$ -dystroglycan fragments of 60 and 120-130 kDa may be detected since there are monoclonal antibodies directed against  $\alpha$ -dystroglycan. It is further inherent that the medium may be blood, tumorigenicity may be measured by detecting the presence or absence of  $\alpha$ -dystroglycan on the presence of cells, and by measuring the amount of  $\alpha$ -dystroglycan to  $\beta$ -dystroglycan. Accordingly, the reference anticipates the invention as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


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Natalie A. Davis, PhD

April 18, 2002

  
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